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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE



In re Application of )  
Saswati CHATTERJEE, et al. )  
Serial No. 09/453,801 ) Examiner: G. Leffers Jr.  
Filed: December 3, 1999 ) Group Art Unit: 1636  
For: METHOD OF GENETICALLY MODIFYING VERY PRIMITIVE  
QUIESCENT HUMAN HEMATOPOIETIC STEM CELLS)

DECLARATION UNDER 37 C.F.R. §1.131

Dear Sir:

1. We, Saswati Chatterjee, Kamehameha K. Wong, Jr., and Christie Ann Wong, hereby declare as follows:
2. I am an inventor of the invention disclosed and claimed in the above-referenced application.
3. On a date prior to November 15, 1998, we conceived the subject invention in the United States.
4. Attached hereto as Exhibit 1 are photocopies of pages from laboratory notebooks of Christie Ann Wong, printouts of electronic data files from corresponding experiments, and photographs of chromosomes with integrated vector sequences. The dated notebook pages show this work was completed prior to November 15, 1998, although the actual dates have been deleted from the attached copies.

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5. The photocopies are true and exact copies of the original notebook pages, with the exception that the dates on which the entries were made have been obliterated. The entries in the original notebook pages were made by Christie Ann Wong contemporaneously with the experimental work described therein and were dated at the time the entries were made. Each of the entries in the original notebook pages of Exhibit 1 were made prior to November 15, 1998.
6. The laboratory notebook pages, electronic data files and photographs show isolation and characterization of a CD34<sup>+++</sup> G0 cell population and CD34/CD38 profile with computer-generated table of fluorescence *in situ* hybridization (FISH) data showing vector integration in cells from donor AA 4, 6 and 8 weeks after transduction (Exhibit 1); PCR analysis of colonies derived from these CD34<sup>+++</sup> cells in G0 (Exhibit 2); FISH results showing rAAV transduction and stable introduction into CD34<sup>+++</sup> cells in G0 from donors VB and JB (Exhibit 3); data and experimental details of rAAV transduction and FISH analysis of CD34<sup>+++</sup> G0 cells from donors VB and JB, with photomicrographs of FISH on transduced CD34<sup>+++</sup> G0 cells and untransduced controls (Exhibit 4); isolation

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of CD34 G0 cells from donor JG with detailed analysis of G0 cells (Exhibit 5); analysis of transduction of CD34<sup>+</sup> cells in G0 from donor CM (Exhibit 6); kinetic analysis and rAAV transduction of a G0 population (Exhibit 7); and analysis CD34<sup>+</sup> cell subpopulations from donor OM, showing that the CD34<sup>+</sup>CD38<sup>-</sup> cells are in G0 (Exhibit 8).

7. In my opinion, all steps necessary to render the subject invention complete were made in the United States prior to or by the date on which the last of the original pages of Exhibit 1 were dated.
8. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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Saswati Chatterjee

Saswati Chatterjee

Date: 1/4/02

Kamehameha K. Wong, Jr.

Kamehameha K. Wong, Jr.

Date: 1/4/02

Christie Ann Wong

Christie Ann Wong

Date: 1/9/02

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